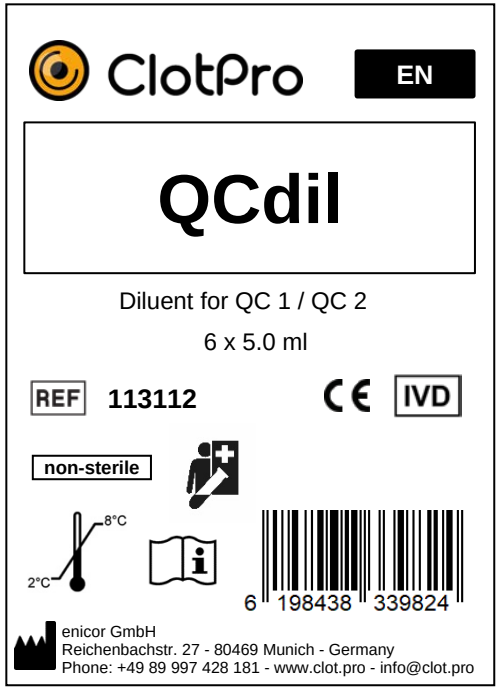

PN 113112-IE (AA) 2021-07

For in vitro diagnostic use.

Intended Purpose

QCdil is a diluent solution for reconstitution of QC 1 and QC 2, required to run quality controls on the ClotPro® analyzer [(1)]. Using QCdil, a semi-automated and semi-quantitative quality control measurement is executed, using the ClotPro analyzer, Cups and Pins, the respective Active Tip, and QC1 or QC2 material.

Intended User

For use by trained healthcare professionals. Near patient and laboratory professional use.

Package format

6 tubes, each 5.0 ml

Constituents

QCdil is packaged ready for use. The diluent is a mix of calcium chloride (2 mM) and aqua dest.

Reagent handling

Prior to use, QCdil must be pre-warmed to 37 °C by placing the tube in the pre-heating position of the ClotPro analyzer for a minimum of 10 minutes.

1.36 ml QCdil solution reconstitutes one vial of QC 1 or QC 2.

1 tube QCdil contains solution for reconstitution of up to 3 QC vials.

For the reconstitution of QC vials with QCdil, the ClotPro e-pipette may be used as follows: Transfer four times 340 µl QCdil into one QC vial (= 1360 µl). Alternatively, a pipette with a volume preset to 1360 µl may be used to transfer QCdil into the QC vial at once.

Storage and stability

Store tubes at +2 to +8°C.The unopened tubes are stable until the expiration date printed on the tube label. Use the contents of opened tubes within 8 days after first opening.

Warnings and precautions

For use by trained healthcare professionals. Exercise the normal precautions required for handling all laboratory reagents. Disposal of all waste material should be in accordance with local regulations.

Material safety data sheet available for professional user on request. Ensure proper storage conditions. Use the contents of opened tubes within 8 days after first opening. Discard the tube if there is suspicion of contamination with other substances.

Residual Risks

Sources of reagent error:

- Improper use of reagents can lead to wrong test results.

Sources of procedural error:

- A defective electronic pipette or its improper use can lead to incorrect pipetting volumes.
- Poor sample quality due to pre-analytic problems can lead to wrong test results.
- Excessive time elapsed between pipetting steps can lead to wrong test results.

Limitations of the procedure:

Variables such as temperature, storage, instrument properties and individual use techniques may affect the final result. Therefore, strictly follow the manufacturer's guidance on the use of the ClotPro analyzer and reagents[(2; 3)]

Packaging Symbols

Symbol	Description
	Near patient testing
	Remove Cups & Pins from packaging together
	Do not touch the Pins
	Use Cups & Pins together with Active tips™

Revision History

Version	Modification
AA	Initial version acc. to regulation (EU) 2017/746 (IVDR)

Literature

1 Calatzis A., Wittwer M., Leyser H., Hipp Q., Spannagl M. ClotPro – a new generation viscoelastic whole blood coagulation analyser. Hämostaseologie 2018; 4a, A32, P013

2 ClotPro user manual

3 Product Inserts QC 1, QC 2, EX-test, IN-test, TPA-test, HI-test, AP-test, ECA-test, FIB-test, and RVV-test

Technical Assistance

You can contact us for technical assistance – please see contact details below.

Incident Reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Manufacturer

enicor GmbH - Reichenbachstr. 27 - 80469 Munich - Germany - Phone: +49 89 997 428 181 - www.clot.pro - info@clot.pro